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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/067,638 04/28/98 COWSERT

L ISIS-2960

EXAMINER

HM22/0928

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ART UNIT

PAPER NUMBER

1655

DATE MAILED:

09/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/067,638

Applicant(s)

Cowser et al.

Examiner

Ardin Marschel

Group Art Unit

1655

☒ Responsive to communication(s) filed on 7/6/99 and IDSs (filed 9/4/98, 9/18/98, and 8/30/99)

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-46 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 20 sheets

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Raw Sequence Listing ERROR REPORT

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1655.

Applicants' arguments; filed 7/6/99; and IDSs, filed 9/4/98, 9/18/98, and 8/30/99; have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because errors have been found in the submitted CRF sequence. See the enclosed CRF Diskette ERROR REPORT. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

Claims 1-46 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 1-46 as being vague and indefinite

is reiterated and maintained from the previous office action, mailed 12/28/98. As set forth previously the "defined criteria" lack any even obscure or unclear connection to binding or whatever other limitations in the claims. The word "defined" suggests some definition of some sort. None has been either amended into the claims nor argued as being defined leaving the claims still vague and indefinite. That is, what "defined criteria" are meant for the practice of these claims? Also, as noted in the previous office action, the preamble cites the modulation of expression confusingly without any steps that are directed to such modulation of expression. Binding to target nucleic acids may modulate expression but not without expression components being present such as enzymes, cofactors, etc. Since, none of these components are required in the instant claims, as noted in the previous office action, the instant claims are undefined as to how modulation of expression is connected to said defining, identifying, etc. In summary, the claims remain vague and indefinite as noted in the previous office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled

the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-46 are rejected under 35 U.S.C. § 102(e) as being clearly anticipated by Peterson et al. (P/N 5,783,431).

This rejection of claims 1-46 under 35 U.S.C. § 102(e) is reiterated and maintained from the previous office action, mailed 12/28/98. Applicants argue firstly that Peterson et al. fails to teach actual construction of combinational gene expression libraries. In response the instant claims are not limited to requiring the construction of such libraries either but broadly only to "defined criteria"?? Also, the generation of expression libraries was cited in Peterson et al. previously at columns 6, 34, and 35. Applicants then argue that the reference does not generate or evaluate compounds or binding "in silico". In response, applicants are reminded that the "in silico" has been instantly defined in the instant specification on page 8 as "in a computer manipulatable and reliable form". Peterson et al. was previously noted as describing robotic screening in column 14, lines 5-21, which citation includes high throughput screening which clearly is computer manipulatable via robotics, cited in Peterson et al., and reliable as being performed in such a system oriented to high throughput that is well known to be utilized for highly reproducible and repetitive procedures. In summary, the rejection is maintained and reiterated from the previous office

action, mailed 12/28/98.

Enclosed are several sheets of PTO Form 1449. On page 17 of the IDS, filed 9/4/98, three applications for U.S. Patents were listed. The first two have matured into U.S. Patents and are listed as having been considered on the enclosed PTO Form 892. The third with serial number 08/762,488 is confusing because it is not a Cook application, nor is of Cook type subject matter, nor has matured into a U.S. Patent. Therefore, it has not been considered regarding the instant application.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

September 27, 1999

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER